No. 17-1229

IN THE

Supreme Court of the United States

HELSINN HEALTHCARE S.A.,

Petitioner,

v.

TEVA PHARMACEUTICALS USA, INC., *et al.*,

Respondents.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF OF *AMICUS CURIAE* INTELLECTUAL PROPERTY OWNERS ASSOCIATION IN SUPPORT OF NEITHER PARTY

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I

INTEREST OF *AMICUS CURIAE*

Amicus curiae Intellectual Property Owners Association (IPO) is an international trade association representing companies and individuals across all industries and fields of technology who own or are otherwise interested in intellectual property rights.[1] IPO's membership includes about 200 companies and over 12,000 individuals who are involved in the association, either through their companies or as inventor, author, executive, law firm, or attorney members. Founded in 1972, IPO represents the interests of all owners of intellectual property before Congress and the United States Patent and Trademark Office (USPTO), and has filed *amicus curiae* briefs in this Court and other courts on significant issues of intellectual property law. The members of IPO's Board of Directors, which approved the filing of this brief, are listed in the Appendix.[2]

INTRODUCTION

IPO's members invest tens of billions of dollars annually on research and development, employing hundreds of thousands of scientists, engineers, and others in the United States to develop, produce, and market

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1. No counsel for a party authored this brief in whole or in part, and no such counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than the *amicus curiae* or its counsel made a monetary contribution to its preparation or submission. Both parties have consented to the filing of this brief.

2. IPO procedures require approval of positions in briefs by a two-thirds majority of directors present and voting.

innovative new products and services. Many of these innovations take years of research, failure, missteps, and refinements to reach eureka moments, and still additional time to develop practical applications followed by potential commercialization.

Because of the need to timely file for patents on their innovations, this case presents a question of substantial practical importance to IPO members: namely, whether in enacting the Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) (AIA) Congress changed the on-sale bar defense to exclude "secret sales" where the invention is not made public. IPO, the trial court, and the USPTO have all concluded that Congress did indeed make such a change to the on-sale bar defense; a determination with which the Federal Circuit disagreed. This Court's resolution of the proper application of the on-sale defense post-AIA is consequential because it will instruct IPO members, as well as the parties, and indeed all intellectual property stakeholders, how to conduct their business and protect their innovations without triggering an on-sale bar.

SUMMARY OF ARGUMENT

At issue on appeal is whether Congress changed the "on-sale" bar to patentability raised as a defense to a patent infringement assertion in enacting the AIA in two aspects: first, whether the post-AIA on-sale bar excludes private sales; and second, whether a public sale requires that the claimed invention subject to the sale be made public to be invalidating.

The U.S. Court of Appeals for the Federal Circuit (Federal Circuit) held that Congress did not "change the statutory meaning of 'on sale'" by enacting the AIA, *Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc.*, 855 F.3d 1356, 1360 (Fed. Cir. 2017). The Federal Circuit decision, however, is contrary to the fundamental policy underlying the patent system of encouraging innovation by awarding patents for the public disclosure of the innovation to be protected. Also lost is the practical reality of operations in the present global economy that many complex innovations require arms-length collaboration with third parties to refine and bring those innovations to market. In addition, the Federal Circuit decision disregards the proper tenets of statutory construction and the meaning of "available to the public" as recited by the post-AIA on-sale bar, as well as the apt legislative history.

The Federal Circuit's holding that the mere existence of a public sale or offer for sale that does not disclose the invention as claimed is inconsistent with that part of the Federal Circuit's *en banc* decision in *Medicines Co. v. Hospira, Inc.*, 827 F.3d 1363 (Fed. Cir. 2016) stating that "the offer or contract for sale must unambiguously place the invention on sale, as defined by the patent's claims." *Helsinn*, 855 F.3d at 1366. It also finds no support in this Court's precedence and is inconsistent with the USPTO's post-AIA examination guidelines, adopted before the AIA became effective and still followed today. *See* U.S. Patent and Trademark Office, Manual of Patent Examining Procedure § 2152(d) (9th ed., 08.2017 rev., revised Jan. 2018) (MPEP). These examination guidelines were previously the only authoritative guidance post-AIA on whether an invention was on-sale to bar patentability. Indeed, the USPTO's guidelines have governed examination of many hundreds of thousands of patent applications.

More post-AIA innovations are being made, applications are being filed, and patents are being issued every day— the validity and value of many of those patents will remain clouded until this Court settles the present on-sale bar debate. Similarly, both large and small innovators and their business partners need clarity now, so they can organize their businesses and contracts to develop and commercialize innovations while mitigating risks to protection when contracting with others to bring such innovations to market.

IPO believes Congress intended, and that it is the best policy for the U.S. patent system that under the AIA an inventor's sale of an invention to a third party that is obligated to keep the invention confidential does not trigger the on-sale bar and does not qualify as prior art for purposes of determining the patentability of the invention as claimed in a later filed patent application.

ARGUMENT

I. Proper Application of the Post-AIA On-Sale Bar Is Critically Important to All Industries and Fields of Technology

This case presents an important issue of first impression: whether Congress substantively changed the on-sale bar in section 102 of the Patent Act when it enacted the AIA. Congress made fundamental changes to the Patent Act by, among other things, redefining prior art under section 102. *See Helsinn*, 855 F.3d at 1368. The Federal Circuit expressly declined, however, to address how those changes, which it deemed limited to "public use" activities, affect application of the on-sale bar, *see*

id. at 1368-69, a critically important issue that this Court should decide.

Interpretation of the post-AIA on-sale bar as requiring public disclosure of the invention is consistent with a policy of encouraging innovation and recognizing that many complex technological developments require collaboration with third parties to refine and commercialize inventions. Indeed, to bring new products and services to market, smaller inventors often resort to contractual arrangements with third parties for supply and/or distribution because size and capital constraints prevent the internal execution of such functions. Other inventors that have deep internal resources might or might not contract with third parties to bring their innovations to market. Regardless, complexity in factors such as manufacturing, supply chain, and distribution in many industries dictates that plans for commercialization begin years before research and development has produced marketable products, particularly, for example, in the pharmaceutical, semiconductor, energy, aerospace, and automotive industries.

By way of specific example, there exists a close working relationship in the semiconductor industry between chip manufacturers and semiconductor processing equipment suppliers. In this innovation ecosystem, chip manufacturers often focus on product design, relying on equipment suppliers to design and build manufacturing equipment to fabricate such designs. Although chip manufacturers focus on chip design, they also develop new processing inventions to help achieve particular design features. In those cases, the chip manufacturer works with an equipment supplier to develop equipment that can execute such processing inventions. In such

circumstances, purchase agreements for equipment that implements those new processing inventions could give rise to an on-sale bar under the Federal Circuit's current interpretation of the law.

Other examples are found in the aerospace and automobile industries. There, similar relationships exist between the innovator and the suppliers who must plan often years in advance of commercialization of an invention, to develop the tools and processes to supply components and substructures first as prototypes to establish proof of concept, and if successful later as commercially viable components for commercial release. In these circumstances too, arm's length agreements regarding the development and supply of components could give rise to an on-sale bar under the Federal Circuit's current interpretation of the law.

It goes without saying that the biopharmaceutical industry, as presented by the facts of this case, presents another important example.

Allowing innovators to enter into sales contracts with third parties provides a means for developing innovations that might not come to fruition without third party collaboration, an outcome that appears to frustrate the purpose of the patent laws. Such freedom allows inventors to contribute innovations where they would not otherwise have the capital infrastructure or other necessary resources to fully refine an invention, while also fostering the development of inventions that require experience across several industry or technical domains. Although third party sales and collaboration have historically been prevalent in certain industries, such activities are becoming ever more important

across an increasing number of industries, for example, technological integration of hardware and software in industries proliferating around the Internet of Things (IoT) and Artificial Intelligence (AI).

II. The Post-AIA On-Sale Bar Provision Should Be Interpreted to Exclude Secret Sales

a. Statutory Construction Principles Confirm That Congress Intended to Exclude Secret Sales from the On-Sale Bar

When Congress amended the on-sale bar provision of section 102, it added the phrase "or otherwise available to the public." A comparison of the old and current on-sale bar provisions are presented below.

Pre-AIA 35 On-Sale Bar, 35 U.S.C. § 102(b)	35 U.S.C. § 102(a)(1)
A person shall be entitled to a patent unless – ... (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States	(a) Novelty; Prior Art. – A person shall be entitled to a patent unless-- (1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention

Although the Federal Circuit considered Petitioner's statutory construction argument, it found that the "series-modified" doctrine was not applicable (Concurrence *En Banc* Decision at 6-9) and thus determined that the statute did not exclude secret sales. The Federal Circuit's interpretation of the statute, however, does not give effect to the "otherwise available to the public" language added by Congress. This Court has held that a reading of a statute that gives an amendment no effect cannot be correct. *See Pierce City v. Guillen*, 537 U.S. 129, 145 (1995) ("[W]hen Congress acts to amend a statute, we presume it intends its amendment to have real and substantial effect.").

Conversely, a plain reading of the statute and canons of statutory construction confirm that secret sales are excluded from the on-sale bar because "or otherwise available to the public" modifies "on sale." Beyond such an interpretation giving effect to all language comprising the amended statute, courts have consistently construed the words "or otherwise" or "or other" at the end of a string as modifying the preceding clauses. *See, e.g., Strom v. Goldman, Sachs & Co.*, 202 F.3d 138, 146-47 (2d Cir. 1999), *abrogated on other grounds; Universal City Studios, Inc. v. Reimerdes*, 111 F. Supp. 2d 294, 325 (S.D.N.Y. 2000).

Dictionary definitions and the plain meaning of the word "otherwise" refer to a "different" or "other way." In this case, a different or other way that the invention can be made available to the public. *See, e.g.*, Brief of *Amicus Curiae* US Inventor, Inc. in Support of Petitioner Helsinn Healthcare S.A.'s Petition for a Writ of Certiorari at 10-11. Further in this regard, under the principle of *noscitur a sociis*, *i.e.*, a word is known by the company it keeps, the

phrase "on sale" should be interpreted by association with the phrases around it, namely, "in public use" and "otherwise available to the public." *See Yates v. U.S.*, 135 S. Ct. 1074, 1085 (2015) ("[W]e rely on the principle of *noscitur a sociis*—a word is known by the company it keeps— to avoid ascribing to one word a meaning so broad that it is inconsistent with its accompanying words, thus giving unintended breadth to the Acts of Congress.") (citation and internal quotation marks omitted).

The Federal Circuit has thus improperly broadened the on-sale bar post-AIA by disregarding language Congress added to the statute that requires the invention on-sale be made available to the "public" to qualify as prior art.

b. The Legislative History of the AIA Confirms That Secret Sales Were Meant to Be Excluded

The AIA legislative history is replete with commentary from Congress regarding the amendments to section 102(a). These statements confirm that it was Congress' intent to limit non-patent prior art to that which is available to the public.

In 2008, Senator Kyl explained that the patent system will be "simpler and more transparent ... [b]y eliminating confidential sales and other secret activities as grounds for invalidity and imposing a general standard of public availability." 154 Cong. Rec. S9992 (daily ed. Sept. 27, 2008) (statement of Sen. Kyl). This change to section 102(a) would "provide greater certainty and predictability," as well as "substantially reduce the need for discovery in patent litigation, since defendants will no longer need to

uncover evidence of private sales or offers for sale or other nonpublic information in order to determine whether the patent is valid." *Id.*; *see also* 157 Cong. Rec. S5319 – S5320 (daily ed. Sept. 6, 2011) (statement of Sen. Kyl) ("The main benefit of the AIA public availability standard of prior art is that it is relatively inexpensive to establish the existence of events that make an invention available to the public.").

In the March 2011 Senate debate on the AIA, Senator Kyl explained that the word "otherwise" was added to section 102(a) to eliminate secret sales:

> Another aspect of the bill's changes to current section 102 also merits special mention. New section 102(a)(1) makes two important changes to the definition of non-patent prior art. First, it lifts current law's geographic limits on what uses, knowledge, or sales constitute prior art. And second, ***it limits all non-patent prior art to that which is available to the public.*** This latter change is clearly identified in Senate Report 110–259, the report for S. 1145, the predecessor to this bill in the 110th Congress. ***The words "otherwise available to the public" were added to section 102(a)(1) during that Congress's Judiciary Committee markup of the bill. The word "otherwise" makes clear that the preceding clauses describe things that are of the same quality or nature as the final clause— that is, although different categories of prior art are listed, all of them are limited to that which makes the invention "available to the public."*** As the committee report notes at page 9, ***"the phrase 'available***

> ***to the public' is added to clarify the broad scope of relevant prior art, as well as to emphasize the fact that it [i.e., the relevant prior art] must be publicly available.*** In other words, as the report notes, "[p]rior art will be measured from the filing date of the application and will include all art that publicly exists prior to the filing date, other than disclosures by the inventor within one year of filing.

157 Cong. Rec. S1370 (daily ed. Mar. 8, 2011) (statement of Sen. Kyl) (emphasis added).

Congress was well aware of the principles of statutory construction during the drafting of amendments to section 102(a), and intended for the phrase "or otherwise available to the public" to modify and restrict the preceding phrases "in public use" and "on sale":

> The Committee's understanding of the effect of adding the words "or otherwise available to the public" is confirmed by judicial construction of this phraseology. ***Courts have consistently found that when the words "or otherwise" or "or other" are used to add a modifier at the end of a string of clauses, the modifier thus added restricts the meaning of the preceding clauses.*** ... In other words, the Judiciary Committee's design in adding the 2007 amendment to section 102(a)(1), as expressed in the relevant committee report, is consistent with the unanimous judicial construction of the same turn of phrase. It appears that every court that has considered this question agrees with

> the committee's understanding of the meaning of this language. Moreover, ***the fact that the clause "or otherwise available to the public is set off from its preceding clauses by a common confirms that it applies to both "public use" and "on sale"*** .... Thus new section 102(a)(1) imposes a public-availability standard on the definition of all prior art enumerated by the bill—an understanding on which the remainder of the bill is predicated.

157 Cong. Rec. S1370 (daily ed. Mar. 8, 2011) (statement of Sen. Kyl) (emphasis added); ***see also*** 157 Cong. Red. S5431 (daily ed. Sept. 8, 2011 (statement of Sen. Kyl) ("When the committee included the words 'or otherwise available to the public' in section 102(a), ***the word 'otherwise' made clear that the preceding items are things that are of the same quality or nature. As a result, the preceding events and things are limited to those that make the invention 'available to the public.'***") (emphasis added).

Apart from Senator Kyl, Senator Leahy, one of the lead sponsors of the AIA, confirmed that "subsection 102(a) was drafted in part ***to do away with*** precedent under current law that ***private offers for sale*** or private uses or secret processes practiced in the United States that result in a product or service that is then made public may be deemed patent-defeating prior art." 157 Cong. R. S1496 (daily ed. Mar. 9, 2011) (statement of Sen. Leahy) (emphasis added).

Policy reasons guided Congress' changes to section 102(a) because "the [prior] on-sale bar impose[d] penalties not demanded by any legitimate public interest. There is

no reason to fear 'commercialization' that merely consists of a secret sale or offer for sale but that does not operate to disclose the invention to the public." 157 Cong. Rec. S1371 ("The current forfeiture doctrines have become traps for unwary inventors and impose extreme results to no real purpose."). The changes to the on-sale bar provision were highlighted by Senator Kyl because "the bill's imposition of a general public availability standard and its elimination of secret prior art ... are no small matter." *Id.*

Thus, Congress believed that allowing "private and non-disclosing uses and sales to constitute invalidating prior art" under section 102(a) "would be fairly disastrous for the U.S. patent system" and the validity of patents would "depend on discovery-intensive searches for secret offers for sale and non-disclosing uses by third parties." *Id.* Moreover, eliminating secret sales from the on-sale bar was considered "a necessary accompaniment to [the] elimination of geographic restrictions on the definition of prior art" because invalidating secret offers for sale in foreign countries might "place U.S. inventors at grave risk of having their inventions stolen through fraud." *Id.* This was a risk that Congress was not willing to accept. *Id.*; *see also* 157 Cong. Rec. S5320 (daily ed. Sept. 6, 2011) (statement of Sen. Kyl).

The Federal Circuit's dismissal of the legislative history because it was tied to overruling case law related to public use, but not the on-sale bar, does not withstand scrutiny. First, the legislative history does support a construction that excludes secret sales from the on-sale bar, and second, the same policy that excludes secret uses also supports excluding secret sales, as this Court has long recognized. *See Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55,

68 (1998) (citing to a private use case to support when an invention is ready for patenting in determining whether the on-sale bar is met).

III. Excluding Secret Sales Is Consistent with Congress' Intent for the AIA to Harmonize United States Patent Laws with Other Countries

Section 3(o) of the AIA notes Congress' intent to harmonize United States Patent laws with those of other countries:

> SENSE OF CONGRESS.--It is the sense of the Congress that converting the United States patent system from "first to invent" to a system of "first inventor to file" will promote the progress of science and the useful arts by securing for limited times to inventors the exclusive rights to their discoveries and provide inventors with greater certainty regarding the scope of protection provided by the grant of exclusive rights to their discoveries.

This statement recognizes that the pre-AIA statutory structure embraced a first-to-invent system, whereby an inventor did not have to be the first to file a patent application on an invention and could show that he or she had possession of the invention prior to another to be entitled to a patent. Given the first-to-invent approach, there was a desire to make sure inventors timely filed their patent applications and did not commercialize their invention and then later file an application. Thus, the pre-AIA on-sale bar served the purpose of encouraging timely application filings.

The post-AIA statutory structure is different. It adopted the approach used by almost all other countries, whereby the application filing date dictates what is and what is not prior art with respect to that application. In those other countries, secret sales, *i.e.*, sales that did not publicly disclose the invention, were not and are not considered prior art. Accordingly, construing the on-sale bar provision to include secret sales would frustrate the Sense of Congress.

IV. The Federal Circuit Decision Is Inconsistent with Other Interpretations of the On-Sale Bar

Putting aside that Congress redefined "on-sale" post-AIA to exclude sales where the invention is not made known to the public, the result below is inconsistent with *Medicines*, this Court's precedence, and the USPTO's examination guidelines implementing the AIA. It should not stand.

a. The Federal Circuit's *En Banc* Decision in *Medicines* Compels a Result That the Invention Was Not On-Sale in the Present Case

Medicines allows inventors to contract for manufacturing services without triggering the pre-AIA on-sale bar, provided their inventions (as defined by a patent's claims) are not "on sale." 827 F.3d at 1374 (application of the on-sale bar "requires that 'the invention' be 'on sale'" and "[t]he 'invention' is defined by the patent's claims.") (quoting 35 U.S.C. § 102(b)). *Medicines* further states that, "there must be a commercial sale or offer for sale. The statute itself says the invention must be 'on sale,' or that there must be an offer for sale of the invention....

The on-sale bar is triggered by actual commercial marketing of the invention, not preparation for potential or eventual marketing. . . . It is well settled that mere preparations for commercial sale are not themselves 'commercial sales' or 'commercial offers for sale' under the on-sale bar." *Id.* at 1377.

The Federal Circuit, however, has held that the post-AIA on-sale bar applies to all public sales, including sales that do not disclose an invention as defined by the patent claims, holding that "an invention is made available to the public when there is a commercial offer or contract to sell a product embodying the invention and that sale is made public" and that ("after the AIA, if the existence of the sale is public, the details of the invention need not be publicly disclosed in the terms of sale." *Helsinn*, 855 F.3d at 1370-71.

This result is inconsistent with *Medicines* in at least two respects. First, the Federal Circuit decision does not allow inventors the same flexibility for contracting with third parties for license and distribution agreements that must be publicly disclosed that *Medicines* allows for manufacturing agreements that need not be disclosed. Yet neither makes the invention known to the public and there is no principled basis to support inconsistent results.

Second, *Medicines* makes it crystal clear that the alleged sale must unambiguously place the invention on sale and be actual commercial marketing. An inventor's contract, whether for manufacturing or licensing, public or private, amounting to mere preparation for the potential or eventual commercialization does not amount to an invalidating offer for sale, or sale. To hold otherwise would

illogically penalize small innovators who must rely on third parties to prepare for commercialization. Moreover, such a result would serve to doubly penalize small innovators who collaborate with companies having public reporting obligations. It results in further unfair treatment relative to vertically integrated innovators who perform the exact same conduct—except that all such activities are under one corporate roof—to prepare for commercialization in the same way. In both circumstances, however, the claimed invention is not yet disclosed to, or used by the public.

b. The Federal Circuit's Decision Does Not Square with *Pfaff*'s Requirement That the Invention Be Public to Be On Sale

This Court's most recent consideration of the on-sale bar reviewed the origins and policy underpinnings of the doctrine, as well as confirmed that the on-sale bar applies "when two conditions are satisfied before the critical date. First, the product must be the subject of a commercial offer for sale.... Second, the invention must be ready for patenting." *Pfaff*, 525 U.S. at 67. In reaching this two-part test, the Court consistently noted that the invention claimed had to be given up to the public to be on-sale. *See id.* at 64 ("§ 102 of the Patent Act serves as a limiting provision, both excluding ideas that are in the public domain from patent protection and confining the duration of the monopoly to the statutory term.... A similar reluctance to allow an inventor to remove existing knowledge from public use undergirds the on-sale bar."); *see id. at* 65 ("The patent laws therefore seek both to protect the public's right to retain knowledge already in the public domain and the inventor's right to control whether and when he may patent his invention."). But the

Court has not before held that the on-sale bar applies to non-public sales, particularly conditional sales made prior to any actual commercialization where, although the fact of the conditional sale was known, the invention claimed was neither known to nor used by the public.

The Federal Circuit's extension of the on-sale bar to non-public sales has no support in this Court's precedence, does not cite any compelling rationale for such an extension, and should be rejected. In this regard, the Concurring Opinion reveals an inexplicable inconsistency in the Federal Circuit's holding. On the one hand, the Federal Circuit rejected the legislative history argument that the post-AIA on-sale bar excludes secret sales because the cases discussed by Congress were *public use* cases, but "not any *sale* cases that would be overturned by the amendments." *Helsinn* 855 F.3d at 1369. On the other, the Concurring Opinion embraced this Court's endorsement of the general principles set forth in a *public use* case, *Metallizing Eng'g Co. v. Kenyon Bearing & Auto Parts Co.*, 153 F.2d 516 (2d Cir. 1946), regarding when an invention is ready for patenting. *Helsinn Healthcare S.A. v. Teva Pharms. USA Inc.*, No. 16-1284 (Fed. Cir. Jan. 16, 2018), slip op. at 3-4 n.1 (O'Malley, Circuit J., concurring in the denial of panel rehearing) ("[T]he Supreme Court seems to have endorsed the general principles articulated in *Metallizing*."). Rolling back the Federal Circuit's expansion of the on-sale bar to exclude non-public sales would resolve the inconsistency and comport with both Congress's intent and *Pfaff*, which consistently refers to the need for the invention to be "public" to be on sale.

c. The USPTO's Post-AIA View of the Scope of the On-Sale Bar Excludes Secret Sales

Before the effective date of the AIA, the USPTO adopted its interpretive guidelines, including the only authoritative interpretation of new AIA section 102 until the Federal Circuit decision. *See* MPEP § 2152.02(d). For the last five years, patent applicants and examiners have followed those guidelines in considering what information to disclose and the significance of such disclosures. More importantly, the USPTO has examined hundreds of thousands of patents based on a reading of the on-sale bar that is consistent with the district court's construction below, but inconsistent with the Federal Circuit's construction. According to statistics from the USPTO, just under a million patents were granted between 2013 (the year the AIA went into effect) and 2015. *See* USPTO Patent Technology Monitoring Team, U.S. Patent Statistics Chart, Calendar Years 1963-2015, available at https://www.uspto.gov/web/offices/ac/ido/oeip/taf/us_stat.htm (last visited March 17, 2018). These numbers are only increasing as time passes.

As discussed above, the Federal Circuit held that, notwithstanding enactment of the AIA, the on-sale bar applies to a public sale even if an invention is not disclosed in the terms of the sale. *Helsinn*, 855 F.3d at 1371. The USPTO's MPEP, however, takes a different view of the scope of the post-AIA on-sale bar. There, "[t]he phrase 'on sale' in AIA 35 U.S.C. 102(a)(1) is treated as having the same meaning as 'on sale' in pre-AIA 35 U.S.C. 102(b), ***except that the sale must make the invention available to the public.***" MPEP § 2152.02(d) (emphasis added). The USPTO's MPEP further states that "[t]he pre-AIA

35 U.S.C. 102(b) 'on sale' provision has been interpreted as including commercial activity even if the activity is secret.... AIA 35 U.S.C. 102(a)(1) uses the same 'on sale' term as pre-AIA 35 U.S.C. 102(b). ***The 'or otherwise available to the public' residual clause of AIA 35 U.S.C. 102(a)(1), however, indicates that AIA 35 U.S.C. 102(a)(1) does not cover secret sales or offers for sale.*** For example, an activity (such as a sale, offer for sale, or other commercial activity) is secret (non-public) if it is among individuals having an obligation of confidentiality to the inventor." *Id.* (emphasis added).

As the USPTO discusses in formulating its examination guidelines, "[r]esidual clauses such as 'or otherwise' or 'or other' are generally viewed as modifying the preceding phrase or phrases," and that "[t]herefore, the Office views the 'or otherwise available to the public' residual clause of the AIA's 35 U.S.C. 102(a)(1) as indicating that secret sale or use activity does not qualify as prior art." U.S. Patent and Trademark Office, Examination Guidelines for Implementing the First Inventor to File Provisions of the Leahy-Smith America Invents Act, 78 Fed. Reg. 11059-01, 11062 (Feb. 14, 2013)(citations omitted). Further, the USPTO commented "that the Office's interpretation is consistent with the interpretation that was clearly expressed by the bicameral sponsors of the AIA during the congressional deliberations on the measure." *Id.* (citations omitted).

In addition, the USPTO remarked that "interpreting the 'on sale' provision to require public availability is good public policy in that it would lower litigation costs by simplifying discovery and would reduce unexpected prior art pitfalls for inventors who are not well versed in the law." *Id.*

Under the USPTO's post-AIA construction of the on-sale bar, agreements that do not disclose the claimed invention do not bar patentability or invalidate patent claims because the invention claimed has not "made available to the public." The district court found that to be the situation in this case. *See Helsinn Healthcare S.A. v. Dr. Reddy's Labs. Ltd.*, No. CV 11-3962 (MLC), 2016 WL 832089, at *51 (D.N.J. Mar. 3, 2016). This is consistent with *Pfaff's* requirement that the invention be publicly known to be on-sale. Independent of whether any deference is due to the USPTO, the consistency of its construction with the district court's and this Court's precedence and the disagreement between that construction and the Federal Circuit's construction highlights that the Federal Circuit's construction is the outlier that should be reversed.

d. The Concurrence Misapprehends IPO's *Medicines* Argument

Judge O'Malley took issue with IPO's *Medicines* argument in the concurrence to the denial of the petition for *en banc* for this matter, which she described as a mischaracterization of *Medicines*. *Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc.*, No. 2016-1284, 2016-1787, slip op. at 2 (Fed. Cir. Jan. 16, 2018) (O'Malley, J., concurring). Judge O'Malley correctly pointed out that *Medicines*' determination that the agreements at issue did not place the invention on sale was based on a number of factors, including confidentiality, not one of which was "of talismanic significance." *Id.* (citing *Medicines*, 827 F.2d at 1326). IPO agrees, but nevertheless maintains that the weighing of the factors underlying (i) whether the invention was the subject of a commercial sale and (ii) whether the claimed subject matter is made public,

was treated differently and inconsistently in the Federal Circuit decision below, in ***Medicines***, in this Court's precedence, and in the USPTO guidelines, all of which warrants correction by this Court.

Further, the policy discussion in the concurrence below misapprehends IPO's *amicus* position, which is that the Court should determine that Congress changed the on-sale bar, not whether the consequences of applying pre-AIA on-sale bar jurisprudence should be avoided on policy grounds. *Helsinn*, No. 2016-1284, 2016-1787, slip op. at 4-5 (O'Malley, J., concurring). Here, the policy issues bear directly on whether Congress intended to change the on-sale bar to promote innovation, and should be considered in resolving this important question.

In this regard, this Court has previously stated the policy underlying the on- sale bar: "[t]he patent laws therefore seek both to protect the public's right to retain knowledge already in the public domain and the inventor's right to control whether and when he may patent his invention." *Pfaff*, 525 U.S. at 65. After considering that Congress allowed the inventor first a two-year grace period, and then one year, the Court promulgated its two-factor test for the on-sale bar. *Id.* at 65, 67-68. IPO submits this policy focus on "knowledge in the public domain" warrants this Court's confirmation that post AIA the on-sale bar does not embrace secret sales.

CONCLUSION

IPO believes that in enacting the AIA, Congress intended to implement a change in the on-sale bar to exclude secret sales, sales where the invention claimed is not made known to the public, as prior art. The statutory construction, legislative history, and policy of encouraging innovation all support such a result. Moreover, the Federal Circuit failed to consider its *en banc* holding in *Medicines*, the import of this Court's precedence, and the guidance offered by the USPTO that sales must put the invention in the hands of the public before the on-sale bar is triggered.

For these reasons, IPO respectfully requests that this Court confirm that post-AIA § 102(a) requires that a sale must publicly disclose the details of the invention subject to the sale in order to be invalidating.

Respectfully submitted,

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1. IPO procedures require approval of positions in briefs by a two-thirds majority of directors present and voting.

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